REMARKS

Claims 4, 13, 45, 46, and 50 are pending. Claims 5, 6, 7, 8, 9, 14, 15, 16, 17, and 49 have been cancelled. No claims are allowed.

Claim 4 has been amended to recite a "composition" which comprises "isolated" 16 (±4) and 30 (±4) kDa antigens in a "pharmaceutically accepted carrier." The reference to the intended use "for preventing disease in an equid caused by a *Sarcocystis neurona* infection" has been cancelled. The reference to an intended use has been cancelled because while the composition of Claim 4 is useful for treating horses infected with *Sarcocystis neurona*, the composition is also useful for raising antibodies against the 16 and 30 kDa antigens such as taught in Example 1. Claims 13 and 45 have been amended in a similar manner. Support for the amendments can be found on page 13, lines 1-8; page 14, lines 1-31; and, Example 1, which teaches isolation of the antigens by two-dimensional gel electrophoresis.

Claims 13 and 45 have also been amended to recite a method for "treating" a disease in a horse caused by *Sarcocystis neurona*. Support for this amendment can be found on page 10, lines 22-25, and on page 15, lines 8-21, which states that the present invention can be used for prophylactic treatment of

horses to prevent infection by *Sarcocystis neurona* or therapeutic treatment of horses already infected with *Sarcocystis neurona*.

1. Claims 4, 13, and 45 were objected to for using the term "equid" in a context where the term "equine" would be the proper term to use.

Claims 13 and 45 have been amended as suggested by the Examiner to replace the term "equid" with the term "equine". The phrase containing the term "equid" was cancelled in Claim 4.

Reconsideration of the objection is requested.

2. Claims 4-9, 13-17, 45, 46, 49, and 50 were rejected under 35 U.S.C. § 112, first paragraph.

The rejection suggests that the written description does not adequately describe the applicants' claimed invention in such a way as to enable one skilled in the art to make or use the applicants' claimed invention.

Claims 4, 13, and 45 have been amended to recite a "composition" instead of vaccine. Claims 4 and 13 were further amended to recite that the composition contains "an isolated 16 (±4) kDa antigen" and "an isolated 30 (±4) kDa antigen" in "a pharmaceutically accepted carrier". Claims 5, 6, 7, 8, 9, 14, 15, 16,

17, and 49, which are drawn to recombinant polypeptides, fusion polypeptides, and the like, have been cancelled without prejudice.

In light of the above amendments, the applicants believe that the antigen components comprising the applicants' presently claimed composition of Claim 4 and its method of use (Claims 13 and 45) are adequately described in the specification and that the presently claimed method of use is enabled by the specification.

Example 1 provides a two-dimensional electrophoresis method for obtaining the isolated 16 (±4) and 30 (±4) kDa antigens from *Sarcocystis neurona*. The monoclonal antibodies also taught in Example 1 can be used to confirm the identity of the antigens isolated by two-dimensional gel electrophoresis. The specification at page 14, lines 1-31, provides examples of pharmaceutically accepted carriers. Thus, the specification is believed to adequately support a composition comprising an isolated 16 (±4) kDa antigen and an isolated 30 (±4) kDa antigen in a pharmaceutically accepted carrier. One of ordinary skill in the art, following the teachings of the applicants, can isolate from any *Sarcocystis neurona* the 16 (±4) and 30 (±4) kDa antigens by the method of Example 1 and mix the isolated antigens with a

pharmaceutically accepted carrier to produce the applicants' claimed composition. One of ordinary skill in the art does not need the amino acid sequences of the antigens or the DNA sequences encoding the antigens to be produce the presently claimed composition.

Claims 13 and 45 have been amended to recite methods for "treating" horses infected with *Sarcocystis neurona*. Claim 4 has been amended to cancel reference to the intended use of the composition for preventing disease in horses caused by *Sarcocystis neurona*. Liang, as pointed out by the Examiner, suggests that many horses infected with the whole organism develop effective immunity against the organism which may prevent entry of the organism into the CNS of the horse (Liang: page 1834, second col.). The applicants teach a method for treating horses which comprises administering to the horse a composition containing the 16 (±4) and 30 (±4) kDa antigens. The applicants' method includes therapeutic treatment of horses infected with *Sarcocystis neurona* (specification: page 15, lines 8-21). The claimed method of treatment is consistent with the teachings of Liang and the applicants' response in Paper No. 4. Furthermore, because the amendment to Claims 4, 13, and 45 has replaced the term "vaccine" with the term "composition", the presently claimed composition is not limited to the definition for vaccine

as set forth in Stedman's Medical Dictionary.

In light of the above, presently amended claims 4, 13, 45, 46, and 50 are believed to satisfy both the written description and the enablement requirements of 35 U.S.C. § 112, first paragraph. Reconsideration of the rejection is requested.

3. Claims 4-9, 13-17, 45, 46, 49, and 50 were rejected under 35 U.S.C. § 112, second paragraph.

Claims 13 and 45 have been amended as suggested by the Examiner to replace the term "equid" with the term "equine". The term "equid" has been cancelled in Claim 4.

The term "and/or" in Claim 46 has been replaced with the term "and".

Claims 7, 14, 15, 17, and 49 have been cancelled.

The above amendments are believed to place the claims in a form which satisfies the requirements of 35 U.S.C. § 112, second paragraph.

4. Claims 4 and 13 were rejected under 35 U.S.C. § 102(b) as being anticipated by Liang (1998).

Claims 4 and 13 have been amended to recite a composition containing at the least an "isolated" 16 (±4) kDa antigen and an "isolated" 30 (±4) kDa antigen

in a "pharmaceutically accepted carrier".

The amendments do not read on a composition containing the whole organism. The amendments are believed to distinguish the applicants' presently claimed composition from the "whole organism" composition of Liang which is not in a "pharmaceutically accepted carrier."

The applicants agree with the Examiner that Liang suggests that many horses infected with the whole organism develop effective immunity against the organism that may prevent entry of the organism into the CNS of the horse (Liang: page 1834, second col.). However, Liang does not teach a composition comprising the 16 (±4) and 30 (±4) kDa antigens in a pharmaceutically accepted carrier nor does Liang teach a composition containing "isolated" antigens.

In light of the above, presently amended Claims 4 and 13 claim a composition and a method using the composition which are believed to be patentable over Liang. Reconsideration of the rejection is requested.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attachment is captioned **"VERSION WITH MARKINGS TO SHOW CHANGES MADE."**

In light of the above, presently amended Claims 4, 13, 45, 46, and 50 are believed to be

patentable. Notice of allowance is requested.

Respectfully,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 5, 6, 7, 8, 9, 14, 15, 16, 17, and 49 have been cancelled.

Claims 4, 13, 45, 46, and 50 have been amended as follows.

-4-(Fourth amended)

A [vaccine] composition [for preventing disease in an equid caused by a *Sarcocystis neurona* infection] comprising [a] an isolated 16 (±4) kDa *Sarcocystis neurona* antigen and [a] an isolated 30 (±4) kDa *Sarcocystis neurona* antigen in a pharmaceutically accepted carrier.

-13-(Twice amended)

A method for [preventing disease in] treating an [equid] equine [caused by] with a *Sarcocystis neurona* infection comprising:

(a) providing a composition consisting essentially of [a] an isolated 16 (±4) kDa antigen and [a] an isolated 30 (±4) kDa antigen of *Sarcocystis neurona* in a pharmaceutically accepted carrier; and

(b) [vaccinating] inoculating the [equid] equine with the composition to [prevent the disease]

treat the equine with the *Sarcocystis neurona* infection.

-45-(Twice amended)

A method for [preventing] treating a disease in an [equid] equine caused by a *Sarcocystis neurona* infection which comprises providing a composition which [that] when injected into the [equid] equine causes the [equid] equine to produce antibodies against a 16 (±4) kDa antigen and a 30 (±4) kDa antigen of the *Sarcocystis neurona* [wherein the antibodies prevent] which treats the disease caused by the *Sarcocystis neurona*.

-46-(Amended)

The method of Claim 45 wherein the [vaccine] composition comprises [the] an isolated 16 (±4) kDa antigen [and/or] and an isolated 30 (±4) kDa antigen in a [vaccine] pharmaceutically accepted carrier.

-50-(Amended)

The method of Claim 45 wherein the [vaccine] composition is administered by [a vaccination] an inoculation route selected from the group consisting of intranasal administration, intramuscular injection, intraperitoneal injection, intradermal injection, and subcutaneous injection.